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*Admitted only in Maryland
*Admitted only in Virginia
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May 17, 2002

WRITER'S DIRECT NUMBER: (202) 371-2678

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TC 1700

Commissioner for Patents
Washington, D.C. 20231

Art Unit 1743

Re: U.S. Utility Patent Application
Appl. No. 10/041,605; Filed: January 10, 2002
For: **An In Vitro System for Determining Formation of A β Amyloid**
Inventors: Tanzi *et al.*
Our Ref: 0609.4100001/JAG/JUK

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (28 pages) citing 91 documents;
3. Copies of the 91 documents: AA1, AB1, AC1, AD1, AE1, AF1, AG1, AH1, AL1, AR1, AS1, AT1, AR2, AS2, AT2, AR3, AS3, AT3, AR4, AS4, AT4, AR5, AS5, AT5, AR6, AS6, AT6, AR7, AS7, AT7, AR8, AS8, AT8, AR9, AS9, AT9, AR10, AS10, AT10, AR11, AS11, AT11, AR12, AS12, AT12, AR13, AS13, AT13, AR14, AS14, AT14, AR15, AS15, AT15, AR16, AS16, AT16, AR17, AS17, AT17, AR18, AS18, AT18, AR19, AS19, AT19, AR20, AS20, AT20, AR21, AS21, AT21, AR22, AS22, AT22, AR23, AS23, AT23, AR24, AS24, AT24, AR25, AS25, AT25, AR26, AS26, AT26, AR27, AS27, AT27, and AR28; and
4. A return postcard.

Commissioner for Patents

May 17, 2002

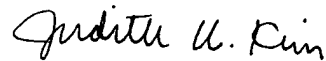
Page 2

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Judith U. Kim
Attorney for Applicants
Registration No. 40,679

JAG/JUK/SJE/tts
Enclosures

SKGF_DC1:13777.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tanzi *et al.*

Appl. No. 10/041,605

Filed: January 10, 2002

For: **An *In Vitro* System for
Determining Formation of A β
Amyloid**

Confirmation No. 5366

Art Unit: 1743

Examiner: *To be assigned*

Atty. Docket: 0609.4100001/JAG/JUK

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Information Disclosure Statement **TC 1700**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AL1 and AS5 cited on Form PTO 1449, for which English translations are not presently available:

Document **AL1**, WO 94/17197, contains a Specification in Japanese and an Abstract in English. A Derwent English language abstract of Document **AL1** is attached as Document **AR28**. The relevance of Document **AL1** can also be ascertained by reference to Document **AT27**, the International Search Report for International Application No. PCT/US94/11895.

Document **AS5** contains an abstract in English.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

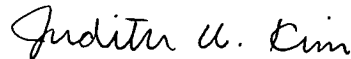
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date, but before the mailing date of a first Office Action on the merits. No statement or fee is required.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

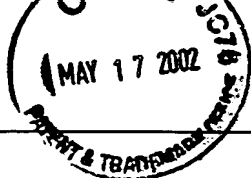
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Judith U. Kim
Attorney for Applicants
Registration No. 40,679

Date: May 17, 2002

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.4100001	APPLICATION NO. 10/041,605
	APPLICANT Tanzi et al.	
	FILING DATE 01/10/2002	GROUP 1743

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,666,829	05/19/1987	Glenner G.G. et al.	435	6	05/15/1985
	AB1	5,164,295	11/17/1992	Kisilevsky, R. et al.	435	7.8	03/06/1991
	AC1	5,231,000	07/27/1993	Majocha R. et al.	435	7.1	07/22/1991
	AD1	5,242,932	09/07/1993	Gandy S.E. et al.	514	313	12/17/1991
	AE1	5,262,332	11/16/1993	Selkoe, D.J.	436	518	09/19/1989
	AF1	5,276,059	01/04/1994	Caughey B. et al.	514	647	07/10/1992
	AG1	5,434,050	07/18/1995	Maggio, J.E. et al.	435	7.21	08/13/1991
	AH1	6,365,414 B1	04/02/2002	Tanzi, R.E. et al.	436	86	08/26/1994
	AI1						
	AJ1						
	AK1						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 94/17197	08/04/1994	WIPO			Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
	AP1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>1</u>	Assaf, S.Y. and Chung, S.H., "Release of endogenous Zn ²⁺ from brain tissue during activity," <i>Nature</i> 308:734-736, Macmillan Magazines, Ltd. (1984)
	AS	<u>1</u>	Backstrom, J.R. et al., "Characterization of Neutral Proteinases from Alzheimer-Affected and Control Brain Specimens: Identification of Calcium-Dependent Metalloproteinases from the Hippocampus," <i>J. Neurochem.</i> 58:983-992, Raven Press, Ltd. (1992)
	AT	<u>1</u>	Baker, R.J. et al., "Platelet Metal Levels in Normal Subjects Determined by Atomic Absorption Spectrophotometry," <i>Thrombos. Haemost.</i> 39:360-365, F.K. Schattauer Verlagsgesellschaft mbH (1978)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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APPLICATION NO.
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APPLICANT
Tanzi *et al.*

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Björkstén, B. <i>et al.</i> , "Zinc and Immune Function in Down's Syndrome," <i>Acta. Paediatr. Scand.</i> 69:183-187, Scandinavian University Press (1980)
	AS	2	Burdick, D. <i>et al.</i> , "Assembly and Aggregation Properties of Synthetic Alzheimer's A4/β Amyloid Peptide Analogs," <i>J. Biol. Chem.</i> 267:546-554, American Society for Biochemistry and Molecular Biology, Inc. (1992)
	AT	2	Bush, A.I. <i>et al.</i> , "The Amyloid Precursor Protein of Alzheimer's Disease Is Released by Human Platelets," <i>J. Biol. Chem.</i> 265:15977-15983, American Society for Biochemistry and Molecular Biology, Inc. (1990)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Bush, A.I. et al., "An Abnormality of Plasma Amyloid Protein Precursor in Alzheimer's Disease," <i>Ann. Neurol.</i> 32:57-65, American Neurological Association (1992)
	AS	3	Bush, A.I. et al., "A Novel Zinc(II) Binding Site Modulates the Function of the β A4 Amyloid Protein Precursor of Alzheimer's Disease," <i>J. Biol. Chem.</i> 268:16109-16112, American Society for Biochemistry and Molecular Biology, Inc. (August 1993)
	AT	3	Bush, A.I. et al., "Modulation of A β Adhesiveness and Secretase Site Cleavage by Zinc," <i>J. Biol. Chem.</i> 269:12152-12158, American Society for Biochemistry and Molecular Biology, Inc. (April 1994)

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Cai, X-D. et al. "Release of Excess Amyloid β Protein from a Mutant Amyloid β Protein Precursor," <i>Science</i> 259:514-516, American Association for the Advancement of Science (January 1993)
	AS	<u>4</u>	Candy, J.M. et al., "Aluminosilicates and Senile Plaque Formation in Alzheimer's Disease," <i>Lancet</i> 1:354-357, The Lancet (1986)
	AT	<u>4</u>	Candy, J.M. et al., "Amorphous aluminosilicates promote nucleation or amyloid β protein and tachykinins," <i>Biochem. Soc. Trans.</i> 21:53S, Portland Press, Ltd. (Abstract) (1992)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Chartier-Harlin, M-C. et al., "Early-onset Alzheimer's disease caused by mutations at codon 717 of the β -amyloid precursor protein gene," <i>Nature</i> 353:844-846, Macmillan Magazines, Ltd. (1991)
	AS	5	Constantinidis, J. et al., "Alzheimer's disease: the zinc theory," <i>Encephale</i> 16:231-239, Masson Editeur (1990)
	AT	5	Corrigan, F.M. et al., "Hippocampal tin, aluminum and zinc in Alzheimer's disease," <i>Biometals</i> 6:149-154, Rapid Communications of Oxford, Ltd. (July 1993)

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	AL						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Crapper McLachlan D.R. et al., "Intramuscular desferrioxamine in patients with Alzheimer's disease," <i>Lancet</i> 337:1304-1308, The Lancet (1991)
	AS	<u>6</u>	Davies, I.J.T. et al., "Measurements of plasma zinc," <i>J. Clin. Pathol.</i> 21:359-365, BMJ/British Medical Journal Publishing Group (1968)
	AT	<u>6</u>	Dawson, R.M.C. et al., "Krebs Mammalian Ringer Solutions," in Data for Biochemical Research, Dawson, R.M.C. et al., eds., 3 rd edition, Oxford University Press, pp.446-448, (1986)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Duncan, M.W. et al., "Zinc, a Neurotoxin to Cultured Neurons, Contaminates Cycad Flour Prepared by Traditional Guamanian Methods," <i>J. Neurosci.</i> 12:1523-1537, Society for Neuroscience (1992)
	AS	7	Esch, F.S. et al., "Cleavage of Amyloid β Peptide During Constitutive Processing of Its Precursor," <i>Science</i> 248:1122-1124, American Association for the Advancement of Science (1990)
	AT	7	Fitzgerald, D.J., Maggio J.E. et al., and Bush A.I. et al., "Technical Comments: Zinc and Alzheimer's Disease," <i>Science</i> 268:1920-1923 (June 1995)

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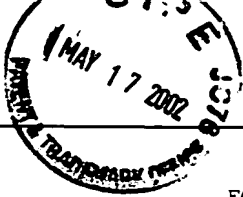
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Folstein, M.F. et al., "'Mini-metal state.' A practical method for grading the cognitive state of patients for the clinician," <i>J. Psychiatr. Res.</i> 12:189-198, Pergamon Press (1975)
	AS	8	Franceschi, C. et al., "Oral zinc supplementation in Down's syndrome: restoration of thymic endocrine activity and of some immune defects," <i>J. Ment. Defic. Res.</i> 32:169-181, Blackwell Science, Ltd. (1988)
	AT	8	Frederickson, C.J. et al., "Cytoarchitectonic Distribution of Zinc in the Hippocampus of Man and the Rat," <i>Brain Res.</i> 273:335-339, Elsevier Science Publishers B.V. (1983)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Frederickson, C.J. et al., "Zinc-containing 7S-NGF Complex. Evidence From Zinc Histochemistry for Localization in Salivary Secretory Granules," <i>J. Histochem. Cytochem.</i> 35:579-583, The Histochemical Society, Inc. (1987)
	AS	9	Frederickson, C.J., "Neurobiology of zinc and zinc-containing neurons," <i>Int. Rev. Neurobiol.</i> 31:145-238, Academic Press, Inc. (1989)
	AT	9	Fredericq, E., "The Association of Insulin Molecular Units in Aqueous Solutions," <i>Arch. Biochem. Biophys.</i> 65:218-228, Academic Press, Inc. (1956)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Galasko, D. et al., "Monitoring Progression in Alzheimer's Disease," <i>J. Am. Geriatr. Soc.</i> 39:932-941, American Geriatrics Society (1991)
	AS	<u>10</u>	Garruto, R.M. et al., "Imaging of calcium and aluminum in neurofibrillary tangle-bearing neurons in parkinsonism-dementia of Guam," <i>Proc. Natl. Acad. Sci. USA</i> 81:1875-1879, National Academy Press (1984)
	AT	<u>10</u>	Garzon-Rodriguez, W. et al., "Soluble Amyloid A β -(1-40) Exists as a Stable Dimer at Low Concentrations," <i>J. Biol. Chem.</i> 272:21037-21044, American Society for Biochemistry and Molecular Biology, Inc. (August 1997)

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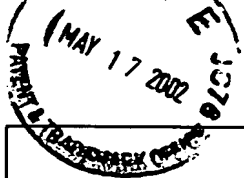
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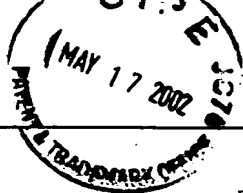
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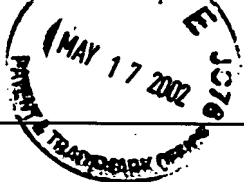
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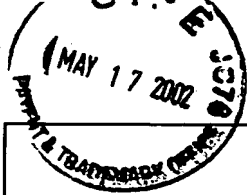
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	24	Suzuki, N. et al., "High Tissue Content of Soluble β 1-40 is Linked to Cerebral Amyloid Angiopathy," <i>Amer. J. Pathol</i> 145:452-460, American Society for Investigative Pathology (August 1994)
	AS	24	Suzuki, N. et al., "An Increased Percentage of Long Amyloid β Protein Secreted by Familial Amyloid β Protein Precursor (β APP ₇₁₇) Mutants," <i>Science</i> 264:1336-1340, American Association for the Advancement of Science (May 1994)
	AT	24	Tanzi, R.E. et al., "Amyloid β Protein Gene: cDNA, mRNA Distribution, and Genetic Linkage Near the Alzheimer Locus," <i>Science</i> 235:880-884, American Association for the Advancement of Science (1987)

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ATTY. DOCKET NO.
0609.4100001APPLICATION NO.
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	AR	<u>25</u>	Tomski, S.J. and Murphy, R.M., "Kinetics of Aggregation of Synthetic β -Amyloid Peptide," <i>Arch. Biochem. Biophys.</i> 294:630-638, Academic Press, Inc. (1992)
	AS	<u>25</u>	Uchida, Y. et al., "The Growth Inhibitory Factor That Is Deficient in the Alzheimer's Disease Brain Is a 68 Amino Acid Metallothionein-like Protein," <i>Neuron</i> 7:337-347, Cell Press (1991)
	AT	<u>25</u>	Vaughan, D.W. and Peters, A., "The Structure of Neuritic Plaques in the Cerebral Cortex of Aged Rats," <i>Neuropathol. Exp. Neurol.</i> 40:472-487, American Association of Neuropathologists (1981)

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	AR	26	Weiss, J.H. et al., "Scientific Correspondence: Zinc and LTP," <i>Nature</i> 338:212, Macmillan Magazines, Ltd. (1989)
	AS	26	Wenstrup D. et al., "Trace element imbalances in isolated subcellular fractions of Alzheimer's disease brains," <i>Brain Res.</i> 533:125-131, Elsevier Science Publishers B.V. (1990)
	AT	26	Wolf, G. et al., "Uptake and subcellular distribution of ⁶⁵ Zinc in brain structures during the postnatal development of the rat," <i>Neurosci. Lett.</i> 51:277-280, Elsevier Scientific Publishers Ireland, Ltd. (1984)

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	AR	<u>27</u>	Xie, X. and Smart, T.G., "A physiological role for endogenous zinc in rat hippocampal synaptic neurotransmission," <i>Nature</i> 349:521-524, Macmillan Magazines, Ltd. (1991)
	AS	<u>27</u>	Yankner, B.A. et al., "Neurotrophic and Neurotoxic Effects of Amyloid β Protein: Reversal by Tachykinin Neuropeptides," <i>Science</i> 250:279-282, American Association for the Advancement of Science (1990)
	AT	<u>27</u>	International Search Report of International Application No. PCT/US94/11895, mailed February 22, 1995.

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	AR	<u>28</u>	Dialog File 351, Accession No. 9996399, Derwent WPI English language abstract for WO 94/17197.
	AS	<u>28</u>	
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